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Patient Care Ombudsman

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: ZHANG MEDICAL P.C., d/b/a NEW HOPE FERTILITY CENTER, Debtor and Debtor-in-Possession	Chapter 11 Case No. 23-10678-PB

PATIENT CARE OMBUDSMAN REPORT

SUBMITTED September 12, 2023

BY:

DAVID N. CRAPO, CIPP-US
PATIENT CARE OMBUDSMAN

I. INTRODUCTION

This Report of the Patient Care Ombudsman ("**PCO**") is issued pursuant to the author's appointment on June 1, 2023 as the PCO by the United States Trustee for Region ("**U.S. Trustee**") for debtor Zhang Medical Center, d/b/a New Hope Fertility Center ("**Debtor**"). The appointment arises under section 333 of the United States Bankruptcy Code (11 U.S.C. §§ 101, *et seq.*), which provides for the appointment of a patient care ombudsman "to monitor the quality of patient care and to represent the interests of the patients of the health care business." The Debtor's operations constitute "health care businesses" for purposes of the Bankruptcy Code. *See* 11 U.S.C. §101(27A). This report covers the period from the PCO's appointment on June 1, 2023 through September 12, 2023.

It is noted that preparation of this report has been hampered and significantly delayed by two factors. The Debtor has not yet provided all of the information requested by the PCO. Additionally, the Food & Drug Administration ("**FDA**") has only recently finalized a report on the Debtor's correction of certain deficiencies the FDA found in a 2021 inspection. The PCO has been in touch regularly with the FDA about the status of that report. FDA has apologized for the delays in its finalization. At the FDA's direction, on August 24, 2023, the PCO filed the required request under the Freedom of Information Request to obtain a copy of the report. To date, the PCO has not been provided with a copy of the report. As discussed below, absent the Debtor's failure to remedy the deficiencies found by the FDA (which the Debtor's representatives contend have been remedied), the PCO has found no evidence of a decline in the quality of patient care and safety at the Debtor's facility.

Review of Publicly Available Information. The PCO has reviewed the Debtor's website on several occasions, most recently on September 12, 2023, as well as employee information provided by the Debtor and determined that the following clinical and laboratory staff are currently employed by the Debtor:

Name of Staff Member	Occupation	License No./Expiry
John Jin Zhang	Physician & Medical Officer	218321 (expires 9/30/23)
Jennifer Kulp-Makarov	Physician	260840 (expires 1/31/25)
Zitao Liu	Physician	277516 (expires 10/31/23)
Khaled Mohamed Zeitoun	Physician	200343 (expires 12/31/24)
Rosario Romano	Physician's Assistant	012127 (expires 1/31/25)

Joanna Tudisco	Nurse Manager	633472 (expires 7/31/2024)
Mariya Shimonov	Nurse Practitioner	421388 (expires 6/30/24)
Hui Liu, PhD	Laboratory Scientist	N/A

The PCO also reviewed the appropriate New York licensing agencies' records and, as noted in the chart immediately above, confirmed that each member the clinical staff is properly licensed. None of the Debtor's clinical staff have been the subject of disciplinary proceedings in the State of New York. None of the clinical staff are on the exclusion list maintained by the Unites States Department of Health and Human Services. The PCO was unable to locate any customer reviews concerning either the Debtor or its clinical staff.

FDA Regulatory Action Against the Debtor. The Debtor has been the subject of a regulatory action by the FDA. The FDA conducted an inspection of the Debtor's facility during November of 2021. Following that inspection, the FDA issued a warning letter, dated June 24, 2022, to the Debtor ("**Warning Letter**"), which the PCO reviewed. The Warning Letter (as well a 41-page Establishment Inspection Report, dated December 17, 2023 also reviewed by the PCO) noted several deviations from appropriate practice at the Debtor's facility. In particular, the FDA noted that not all screening questionnaires had been completed by prospective donors of oocytes or sperm. Similarly, certain policies required by the FDA were incomplete. By correspondence dated July 19, 2022, August 31, 2022 and September 28, 2022, the Debtor: (i) outlined in detail its responses to the FDA's claims in the Warning Letter; (ii) provided the FDA with a detailed corrective action plan, which addressed substantially all of the concerns the FDA outlined in the Warning Letter ; and (iii) outlined, in detail the corrective actions it was taking (including attaching copies of forms revised to meet the FDA's concerns as expressed in the Warning Letter).

By letter dated February 14, 2023 ("**FDA Response Letter**"), the FDA identified three areas not adequately addressed in the Debtor's corrective action plan. Those areas included: (i) addressing screening questionnaires that lack response to questions concerning potential exposure to the Zika virus and the need to quarantine oocytes, semen or embryos provided by the persons preparing the incomplete questionnaires; (ii) the incompleteness of the list of countries with Zika virus risk; and (iii) the reference to regulations not applicable to the Debtor and its facility. By the FDA Response Letter, the FDA advised that it would assess the Debtor's progress on its corrective action plan via an inspection onsite.

The 2023 inspection of the Debtor's facility occurred in April. According to Dr. Julie Bringger of the FDA, a preliminary report was prepared after the inspection, but had to be updated to include new information. Based on the most recent e-mail from Dr. Bringger, which directed the submission of a FOIA request, the report has now been finalized. The PCO expects to receive the report in early October, 2023.

Litigation Aganst the Debtor and Clinical Employees. The Debtor and two of its physicians, John Jin Zhang and Zitao Liu, are the subject of a lawsuit, which is currently pending before the United States District Court for the Southern District of New York: *Juan Cheng and Guo Qiang Chen v. Zhang Medical, PC, et al*. (Civil Action No. 1:21-cv-06682-JGK-SDA). The plaintiffs sued the Debtor and Drs. Zhang and Liu, among others, alleging that their misrepresentations and negligence in performing an IVF procedure resulted in plaintiff Guo Qiang Chen giving birth to a son instead of the daughter she expected.

The plaintiffs allege, among other things, that the Debtor, Dr. Zhang and Dr. Liu have a history of mixing up genetic material, implanting the wrong embryo in patients and hiring unskilled and untrained workers and failing to train them to performed sophisticated medical procedures. However, the PCO's investigation has not uncovered evidence supporting the plaintiffs' allegations in that regard. As noted above, none of the Debtor's clinical staff have been the subject of reported disciplinary proceedings. Additionally, the PCO's research has not uncovered other litigation against either the Debtor or any of its clinical staff. The automatic stay bars any further action in the plaintiff's lawsuit, which had not resulted in the entry of a judgment or an order on a dispositive motion as of the date of the Debtor's bankruptcy filing. Hence, the allegations against the Debtor, Dr. Zhang and Dr. Liu remain just that—allegations.

Inspection of the Debtor's Facility. The PCO inspected the Debtor's facility on August 18, 2023. The facility was clean and well maintained subject to a minimal amount of wear and tear. Clinical and non-clinical staff appeared to treat patients respectfully. There was no indication of understaffing. The safety measures were adequate. Entry into the facility was controlled. Labs and biological specimens were more than adequately protected. Temperature was controlled where temperature control was crucial to the preservation of tissue and other specimens.

The Debtor's blood draw center is clean and well-stocked new equipment. It is staffed by trained phlebotomists, but a nurse practitioner is available for consultation as necessary. The consulting rooms are private with sufficient space for the patient and the clinician. The examination rooms are clean, well-stocked and of sufficient size for purposes. The sonogram rooms are properly equipped and staffed by sonographers or physicians depending on the need.

The operating rooms were clean and sell-stocked. They are used in both retrieval and implantation procedures. They are connected directly to the embryology lab by a window or door. The direct connection of the operating room and the embryology lab minimizes: (i) the chance of contamination of the oocyte or embryo; (ii) accidents involving the oocyte or embryo; (iii) the misidentification of the oocyte or embryo; and (iv) the implantation of an embryo into the wrong patient.

Biohazard materials are properly stored in the appropriate containers. However, the door to the biohazard storage room is not locked. The sperm donor rooms are clean and of adequate size. The embryology lab is clean, well-stocked and well-staffed. The specimen storage areas are clean. The containers are properly sealed and labeled. The area is alarmed to prevent tampering with specimens and to notify staff in the event of a power outage that could result in the loss of temperature control necessary to preserve the specimens.

The Debtor's genomic laboratory is located on the second floor of the building in which the Debtor maintains its facility. It is clean and well-stocked. It is staffed by an embryologist-scientist. Specimens are tested in the lab, as are embryos to determine viability. It is kept locked to prevent the entry of unauthorized persons. Unfortunately, the food smells from a one or more restaurants on the first floor of the building rise to the second floor. However, the laboratory itself is sufficiently insulated to avoid any contamination to the tissue or other specimens that are the subject of testing or research in the laboratory.

One of the Debtor's physicians has her offices on the third floor. There is no embryology lab on the third floor; nor are procedures performed on the third floor. The physician sees patients and consults with them on the third floor. The consulting rooms are clean and of adequate size for the patient and the physician. There are also sonogram/examination rooms that are clean, well-stocked and of adequate size.

Interviews. On August 18, 2023, the PCO interviewed several staff members.

a. Donor Coordinator. The donor coordinator is not a clinician and does not perform procedures. She recruits egg donors, shepherds them through the onboarding process, including the arranging of various clinical appointments. She also makes sure that patients follow medication instructions. When performing these tasks, she ensures that the applicable FDA guidelines are followed. The first step in the donation process is for the patient to fill out a screening questionnaire online. Ms. Liu ensures that the questionnaire is completed and that all questions are answered. Incomplete questionnaires have been a problem, in the past at least, at the Debtor's facility, but the corrective plan the Debtors have in place in response to the Warning Letter, at least in writing, addresses the FDA's concerns. The PCO will need to review the finalized FDA report before being able to actually conclude that the questionnaires are being completed The patient then undergoes testing (which Ms. Liu does not perform) of blood and saliva for genetic and infectious disease screening. The testing could be conducted at New Hope, although it is often conducted at an FDA-approved lab. An outside lab analyzes blood and saliva for infectious disease markers. In any event, the Debtor collects the samples regardless of whether testing will occur onsite or at an outside lab. Potential donors must also submit to a physical examination and a psychological evaluation, which are conducted by outside clinicians. Once the testing is complete, a determination whether a potential donor is eligible is made.

b. Embryologist. One of the embryologists employed by the Debtor explained to the PCO in detail the retrieval and implantation processes to the PCO. At all steps of the process two people are involved in each step to ensure that FDA and other regulations are followed and to provide a confirmation that the appropriate step has been taken. Patients are asked questions at each step of the procedure to ensure that the right patient receives the right treatment or embryo. In connection with the retrieval of oocytes, the patient is asked to identify the dish into which they will be deposited and which is labeled with the patients name. Once oocytes are retrieved and placed in the dish, the medical assistant to the physician performing the procedure passes the dish to the embryology lab telling the embryologist whose oocytes are in the dish, which the embryologist repeats to the medical assistant. Once the oocytes are removed from

the dish they are identified by another embryologist. Forty hours later the sperm is introduced, with the same verification procedures and redundant communications used to maximize the chance that the right sperm is introduced to the right oocyte(s). Thereafter, the patient-oocyte donor will determine whether the embryo will be frozen or implanted. In the case of implantation, the same verification procedures and redundant communications are used to ensure that the correct embryo is implanted into the correct recipient.

c. Medical Director. The PCO interviewed the Debtor's Medical Director. The Medical Director advised confirmed with the PCO that the April inspection had occurred. He agreed to share the closing report with the PCO. The Medical Director characterized the inspection as generally positive. He advised the PCO that the Debtor was making the changes recommended by the FDA. He understood that the FDA's primary concern was the relative paucity of oocyte donors and screening questionnaire's not being completely filled out. He then gave the PCO an overview of the oocyte retrieval and embryo implantation procedures the Debtor provides. Consistent with the Embryologist the PCO interviewed, the Medical Director insisted that the Debtor followed proper identification/confirmation procedures throughout both retrieval and implantation procedures. Every step involves two employees so there are two verifications/confirmations at each step. The Medical Director also confirmed that embryo testing is primarily conducted in-house. He advised the PCO that no outside physicians perform procedures at the Debtors' facilities, thereby eliminating one potential vector of contamination. He advised also that the Debtor does not maintain a sperm bank, but collects sperm only at the time and for the purpose of fertilizing specific oocytes. He also explained to the PCO about clinical coordinators who communicate with patients. In a change from current practice, Nurse Practitioners or Physician's Assistants will be hired to provide those services in the future.

d. Chief Operating Officer. The PCO also interviewed the Debtor's Chief Operating Officer ("**COO**") while the COO escorted the PCO on his inspection of the Debtor's facility. The PCO asked the COO about patient safety, and the COO pointed out the various safety protections the Debtor has in place. The COO also focused on describing how specimens and the labs were protected from tampering by third parties.

Information Requested, but Not Yet Received: The PCO has not received the following information requested from the Debtor. The Debtor's counsel has advised the PCO that she will encourage the Debtor to provide the information shortly. The Debtor's COO contacted the PCO on September 12, 2023 to advise that the following documents will be provided shortly:

- Records that the workforce member has received all required vaccinations, medical tests (*e.g.*, TB tests) and physical examinations.

- Correspondence and communications between the Debtor and any federal, state or local government agency since January 1, 2022, other than the correspondence between the Debtor and FDA you have already forwarded.

- Any notices the Debtor has received since January 1, 2022 from any federal, state or local governmental agency, other than the notices from the FDA you have previously forwarded, and the Debtor's responses to such notices.

- Any written reports memorializing surveys, investigations, reviews, inspections or visits by a federal, state or governmental agency concerning the Debtor's facility since January 1, 2022, other than the reports from the FDA that you have previously forwarded and any responses by the Debtor.

- Any corrective action plan or similar plans required by a governmental agency under which the Debtor has been operating during any period occurring after January 1, 2022.

- Any correspondence or communications between the Debtor and any healthcare accreditation agency during the period beginning January 1, 2022.

- Any notices the Debtor has received since January 1, 2022 from any accreditation agency and the recipient's responses to any such notice.

- Any written reports memorializing surveys, investigations, reviews, inspections or visits by a healthcare accreditation agency with respect to the Debtor or its facility since January 1, 2022 and any responses by the Debtor.

- Any corrective action or similar plans required by a healthcare accreditation agency under which the Debtor has been operating during any period occurring after January 1, 2022.

- Any pre-litigation complaints or threats of litigation the Debtor has received since January 1, 2022 alleging professional incompetence or malpractice on the part of either the Debtor or any of its clinical employees other than in connection with the *Cheng v. Zhang* Medical case.

- Pleadings in any litigation against the Debtor or any of clinical employees alleging professional incompetence or malpractice or breach of contract by the Debtor or any of its clinical employees other than in connection with the Cheng v. Zhang Medical case.

- Evidence that the Debtor and its clinical employees maintain appropriate levels of professional malpractice insurance.

- Evidence that the Debtor's physicians have any necessary privileges at nearby acute care hospitals.

- Reports of any sentinel events, medication errors, patient injuries or deaths connection to treatment by the Debtor

- <u>Policies and Procedures (Copies are Sufficient)</u>

- HIPAA and other data protection policies, procedures and protocols
- Infection control
- Hiring/vetting procedures
- Employee training procedures/orientation
- Employee discipline and termination
    - As well as, records concerning employee discipline and terminations since January 1, 2023
- Quality assurance
    - Including minutes of any meetings of committees charged with ensuring patient care quality
    - Including
- Patient complaint/grievance procedures.
- Medical Records (including compliance measurements)
    - Completion and accuracy
- Patient safety
    - Including records concerning any safety-related incidents.

II. FINDINGS

Based on his review of the publicly available information concerning the Debtor, the PCO has made the following primary findings:

Finding #1: The PCO has not received any information indicating that quality of care provided to the Debtor's patients (including patient safety) is not acceptable and is currently declining or is otherwise being materially compromised, but reserves making an actual finding in that regard pending the receipt of: (i) the information described immediately above that has been requested from the Debtor; and (ii) the finalized report of the FDA on the Debtor's compliance with its corrective action plan.

Finding #2: In light of the lack of any negative information about the Debtor and its clinical staff, the oversight and supervision provided by the Debtor's clinical staff appears to sufficient to uncover quality of care deficits if they arose. The PCO awaits receipt of further documents and information requested from the Debtor, as well as the FDA's finalized report, to make an actual finding on this point.

Finding #3: The PCO's receipt on a regular basis of updates to the information requested from the Debtor should provide a reasonable basis to monitor whether the quality of care (including patient safety) provided by the Debtor is declining or otherwise materially compromised.

III. CONCLUSION

An preliminary analysis of the publicly available sources of information regarding the current performance of the Debtor and its existing structures reveals a facility that apparently continues to provide the same level of patient care and safety it historically provided since before the

Debtor's bankruptcy filing. However, the PCO awaits receipt of the information previously requested from the Debtor and the FDA's finalized report to be able to make actual findings concerning the quality of care (including safety issues) the Debtor's patients are receiving.

. Respectfully submitted to the Court on September 13, 2023 by:

/s/ David N. Crapo
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Patient Care Ombudsman